Remarks

The Examiner has rejected Claims 26-28 and 33-45 under 35 U.S.C. 103(a) as being unpatentable over Niederauer et al. "Evaluation of multiphase implants for repair of focal osteochondral defects in goats," in Biomaterials, Vol. 21, Issue 24, pp. 2561-2574, 15 Dec. 2000. Claims 26-28 and 33-45 have been alternatively rejected and Claims 29-32 have been rejected under 35 U.S.C. 103(a) as being unpatentable over the Niederauer et al. reference in view of Vyakarnam et al. U.S. Patent No. 6,306,424.

The claims have been amended to distinguish over the known references and to claim the invention succinctly. Three independent claims are presented for consideration, i.e., Claim 26, which recites a method for repairing a defect area, Claim 46, a method for making a composite scaffold and Claim 47, a composite scaffold (product). There are 5 dependent claims (48-52) dependent from Claim 47.

The Present Invention Features a Layered Tissue Scaffold with an Interlocked, Porous Polymer/Ceramic Interface with Gradient Porosity

Each of the independent claims expressly recite the structure and functionality of the ceramic/polymer interface that distinguishes the present invention from the references cited. For example, Claim 47 recites: "A composite laminate scaffold with a plurality of substantially parallel layers, comprising

a first of the substantially parallel layers being a ceramic layer formed of a porous ceramic, said porous ceramic defining a three dimensional structure with a first surface, a second surface distal to said first surface and a plurality of macropores

therein, including a plurality of macropores extending from the second surface into the ceramic layer towards said first surface,

a second of the substantially parallel layers being a polymer layer formed of a porous polymer, said porous polymer defining a three dimensional structure with a third surface and a fourth surface distal to said third surface and a plurality of micropores therein, said third surface having **a plurality of projections extending in a direction distal to the fourth surface, said plurality of extensions matingly extending into a corresponding plurality of said plurality of macropores on the second surface of said ceramic layer, a plurality of said plurality of extensions being porous and having at least one micropore communicating with a mating macropore in said ceramic layer, said mating extensions from said polymer layer being formed and matingly received in said corresponding plurality of macropores of said second surface of said ceramic layer, forming a permeable interface region, mechanically interlocking said ceramic layer to said polymer layer.**"

In the highlighted portion of the above-quoted claim, the structure of the interface has been explicitly recited, i.e., the **extensions** with **micropores** that communicate with the **macropores** of the ceramic layer. The extensions which extend into the macropores of the ceramic layer are a recitation of the **mechanical interlocking structure** of the ceramic/polymer interface. The communicating micropores and macropores are an expression that the interface is **permeable**. The use of the terms "micropore" and "macropore", which are defined in the specification (see paragraphs 0028 of the published application) indicate a **gradient porosity** in the

laminate scaffold. (Each of these claimed features and their combination has antecedent basis in the specification. See, e.g., FIG. 1 for depictions of the "extensions".)

The above-described combination of features has important functional implications for a composite tissue scaffold, viz., (i) to allow the transfer of fluids containing metabolites and nutrients through the ceramic/polymer interface to promote cellular ingrowth, in particular in facilitating the healing of a gradient tissue junction, in which (2) a gradient porous structure mimics natural cellular structure at the gradient junction to be healed, while at the same time (3) preserving a physically strong, interlocking junction between the ceramic and polymer layers.

To Applicant's attorney's knowledge, this combination of features is not disclosed in the references cited. For example, Niederauer et al., prescribes "using a small amount of solvent" to glue two polymer layers, one of which optionally contains Bioglass or calcium sulfate particles - hereinafter referred to as the "polymer matrix-ceramic particles layer'. As can be seen from the claim amendments, in addition to pointing out the above-identified important elements of the invention, significant effort has been made to further distinguish the ceramic layer of the present invention, which is now described as (i) being formed from a ceramic, (ii) having a three dimensional structure, (iii) having first and second surfaces, etc., from the "polymer matrix-ceramic particles layer" of Niederauer et al. It should be understood that the "polymer matrix-ceramic particles layer" of Niederauer et al. would exhibit a significantly different bioactivity relative to bone forming cells, in that the polymer matrix would slow cell invasion as compared to a ceramic layer like the present invention - which is why the

ceramic layer of the present invention is positioned next to the bone layer at the site of the injury. Notwithstanding, the claims have been amended to clearly distinguish from a polymer matrix - ceramic particles layer and a ceramic layer in accordance with the claimed invention. However, even if Niederauer et al. disclosed a ceramic layer like that of the present invention, it would still not disclose the claimed features.

More specifically, Niederauer et al. (1) does not disclose infusion of a polymer layer into a ceramic layer (the claimed "extensions" are not present). (2) If there was any overlap of the layer interface, it would not be porous, i.e., the "extensions" would not be porous and would not communicate with pores in the adjacent layer; and (3) the macropore/micropore gradient relationship would not exist.

If simple solvent welding is employed as in Niederauer et al. to join adjacent porous polymer layers, the solvent will dissolve/soften the surface of the solid porous polymer structure to which it is applied, yielding a surface that is "softened" or "wetted with dissolved polymer/solvent". Upon conjunction of adjacent polymer layers, one or more being wetted with solvent, the softened/liquefied surface(s) will conjoin with the adjacent layer and solidify without foaming or pore formation, instead, merely hardening when the solvent evaporates. The implication is that the hardened liquefied polymer, which "glues" the adjacent layers together will be impervious rather than porous.

Neiderauer et al. consistently teaches that the preparation of the constituent polymer layers (before they are glued) requires "kneading and expanding under vacuum and elevated temperatures to produce a porous construct" (see paragraphs 1, 2 and 3 on page 2563 of Niederauer). The description of the solvent

gluing of these same polymer layers does not mention high temperatures or vacuum conditions (necessary conditions for creating a porous construct) for drying the 'solvent glue'. This clearly implies that no "foaming" or other pore creating process is conducted on the 'glue'. One can imagine why pore formation would not be appropriate for a solvent-glued junction, viz., that the resultant glued junction would be distorted and weakened if the small amount of 'glue' resulting from the application of a "small amount of solvent" were 'foamed' or made porous during drying.

Beyond the foregoing limitations, there is no suggestion in Neiderauer that there is any flow or infusion of liquified polymer from one layer into another arising from gluing using a "small amount of solvent." The use of the terminology "gluing" and "using a small amount of solvent" implies that the gross structure of the respective layers is not disturbed. Even if there were some small degree of inadvertent infusion of one dissolved layer into the pores of the adjacent layer, the polymer that is infused will solidify without pores as noted above and therefore the polymer will not have "extensions" with pores that communicate with pores of the adjacent layer. Niederauer et al. is silent as to any relative sizing of the pores of adjacent layers and therefore can not disclose the claimed micropore/macropore gradient.

U.S. Patent No. 6,306,424 to Vyakarnam does not disclose the above-described features th at are missing from the principle reference, e.g., (1) polymer extensions forming (2) an interlocking interface between a ceramic body and a polymer layer, (3) a plurality of the extensions having (4) at least one micropore communicating with a mating macropore in said ceramic layer, etc., and therefore can not supplement the principle reference in formulating a 103 rejection.

U.S. Patent No. 6,306,424 to Vyakarnam is thought to have been owned by the assignee of the present invention at the time that the invention was made and therefore could be removed as a 103 reference in this context. In the event that the Examiner thinks this is necessary, the appropriate statement of Common Ownership will be obtained and filed.

In view of the foregoing, Claim 47 should be allowable over the references.

The Method of Making the Composite Scaffold by Infusing a Ceramic with Polymer and Lyophilizing is Unique

Claim 46 recites a method for making a composite scaffold, comprising the steps of:

"providing a porous ceramic body having first and second surfaces and a plurality of macropores, including macropores extending from within the ceramic body to the second surface;

preparing a polymer solution having a polymer and a solvent;

placing the second surface of said ceramic layer in contact with the polymer solution;

permitting the polymer solution to infuse into a plurality of the macropores extending to the second surface to a given depth within the ceramic body;

foaming the polymer solution by lyophilization to separate the solvent from the polymer in the polymer solution to form a porous solid polymer layer with a plurality of micropores therein, attached to and extending from the second surface of the

ceramic body, **the polymer layer having a plurality of porous polymer extensions extending into a corresponding plurality of the plurality of macropores on the second surface of the ceramic layer into which the polymer solution was infused in the prior step, forming an interlocking interface between the ceramic body and the polymer layer, a plurality of said plurality of extensions having at least one micropore communicating with a mating macropore in said ceramic layer**.

Claim 46 is directed to a method for making and using a scaffold in which a layer of solid polymer is formed integrally on a layer of ceramic (by infusion of liquid polymer solution into the ceramic at a surface and subsequently solidifying and foaming by lyophilization). The claimed process results in the claimed composite scaffold having the attributes of a mechanically interlocked ceramic/polymer interface which is permeable via a gradient porosity. The references do not disclose such steps or resultant features. Accordingly, Claim 46 should be allowable.

Claim 26 incorporates the features of independent apparatus claim, Claim 47 and further includes the steps utilized to apply that novel scaffold to an injured tissue gradient to facilitate repair of same. As a result, Claim 26 should patentably distinguish over the references.

The dependent claims recite additional novel features over and above Claim 47 from which they depend and which has been shown above to be patentable. The dependent claims should therefore be allowable.

Applicant's attorney notes that this small claim set has claims of a type (though lesser in number and having more specific features) than the claims set originally indicated as allowable on April 8, 2003, subsequent to a prior restriction

requirement and response. Using this prior position as a guide and considering that each of the independent claims submitted can be seen to express the essential elements of the invention that have been described above as conferring patentability over the prior art, there should be no problematic issues pertaining to the types of claims presented.

Applicant's attorney respectfully requests the Examiner to allow the claims presented herein. In the event that some detail as to the expression of the invention in the claims is somehow unacceptable, Applicant's attorney respectfully requests the Examiner's assistance to formulate language which in her opinion is satisfactory. Applicant's attorney will likely endorse any reasonable formulation.

A fee in the amount of $490.00 for a two-month Extension Petition is believed to be due. The Petition authorizes the Examiner to charge this $490 fee to Deposit Account No. 503571. In addition, authorization to pay an RCE filing fee is provided on the enclosed Request for Continued Examination Transmittal Form. If any additional fees are due, the Examiner is hereby authorized to charge them to Deposit Account No. 503571.

Respectfully Submitted,

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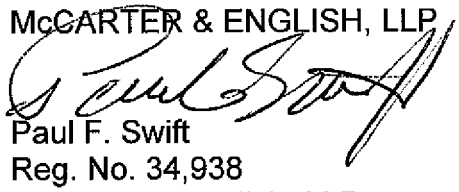

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